Remarks

New claim 58 has been added, the subject matter of which is supported at numerous locations throughout the specification and claims as originally filed and in paragraph ([0054]) and Table 1.

Upon entry of the current amendment, claims 1-16, 18-23, 25 and 50-58 will be pending. Reconsideration and allowance of the claims, as amended, and in light of the following remarks, are respectfully requested.

Claim Rejections - 35 U.S.C. 103

Claims 18-23 and 25 and the term "fenestration"

The Office action rejected claim 25 under 35 U.S.C. 103(a) as being unpatentable over Hogan (U.S. Patent No. 6,569,191; referred to herein as "Hogan") in view of Stack et al. (International Publication No. WO 91/17789; referred to herein as "Stack"), and claims 18-23 as being unpatentable over Hogan in view of Stack and further in view of Cotterman et al. (U.S. Patent Application No. 2002/0153511; herein referred to "Cotterman"). Applicants continue to traverse the rejection of claims 18-23 and 25 as failing to support a conclusion of *prima facie* obviousness.

The Office action has not established that the cited references teach or suggest all the features as recited in the Applicants' claims. Specifically, the Office action has not shown that the cited references teach a bioresorbable, self-expanding stent having a "fenestrated walled surface" that is consistent with the description of the present application.

As the Applicants have stated in their previous response, fenestrated embodiments are clearly described in the specification and claims as originally filed, see paragraphs [0013]-[0014] on pages 1-2; paragraphs [0049]-[0050] on pages 4-5; claims 18-24 and 39-48 as originally filed, and Figure 3. In particular, the "fenestrated" stent embodiments, as described and illustrated, have wall structures that include apertures or holes that are molded or cut into a wall.

The Application clearly distinguishes between embodiments wherein the stent has fenestrations (i.e., a "fenestrated walled surface") and embodiments wherein the stent is formed from braided monofilaments.

While the Office action has stated that, "the specification does not indicate that the term "fenestrations" used in the claims are required to be so formed," Applicants respond that the specification does not describe the spaces between the monofilaments as "fenestrations," but rather, and as clearly described in the application, the fenestrations are molded or cut into a wall. The Office action has also stated in reference to Figure 3 and [0049] that, "the openings 60 formed between the strands and spaced throughout the walled surface 58...are considered to be fenestrations" (emphasis by Applicants). However, this statement is inaccurate because the fenestrated embodiment, as shown in Figure 3, is not described in [0049] as having "strands." "Strands" used in the context of describing the embodiments with braided monofilaments is consistent in both the present application and Hogan.

The Office action has also stated that, "the claims do not even refer to the method of forming the fenestrations." In response, the present claims are not required to recite a method for forming the fenestration, because the specification makes it clear what a "fenestrated walled surface" is. Furthermore, in this regard, these claims have been determined to meet the requirements for 35 U.S.C. 112.

MPEP 2173.01:

> A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought.

The Office action has also stated, "The definition of the term "fenestration" is "an opening in a structure"." However, no reference as to the source of this definition has been provided to the Applicants.

It is noted that this definition is different than the definition of fenestration found in, for example, the Merriam Webster Dictionary, which defines "fenestration" as "an opening in a surface (as a wall or membrane)," and the American Heritage Dictionary, which defines "fenestration" as, "an opening in a surface of a structure, as in a membrane." (emphasis by Applicants)

MPEP 2111.01 states that:

> "In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor."

The term "fenestrated" according to the Merriam Webster and American Hertitage dictionary meanings is clearly the most consistent with term "fenestrated" according as set forth in the present application.

Given the above, the Office action has not established what portions, if any, of Hogan or Stack describe a stent having a "fenestrated walled surface" as recited in claims claim 18-23 and 25.

Because the Office action has not established that the cited references teach or suggest all the features as recited in the Applicants' claims, the requirements necessary for supporting a *prima facie* case of obviousness of claims 18-23 and 25 have not been met, and the outstanding rejection of these claims should be withdrawn.

Claims 1-3, 8-11, 16, 18-23, 50, 51 and 57

The Office action rejected claims 1-3, 8-11, 16, 18-23, 50, 51 and 57 under 35 U.S.C. 103(a) as being unpatentable over Hogan in view Stack and Cotterman et al. (U.S. Patent Application No. 2002/0153511; herein referred to "Cotterman"). Rejection of these claims is traversed as failing to support a conclusion of *prima facie* obviousness.

Applicants continue to assert that the Office action has not shown that the prior art provides a reasonable motivation or suggestion to combine the cited references to arrive at the claimed invention.

The Office action is faced with overcoming the burden of combining references from fundamentally different technologies:

- Bioabsorbable Polymers (Hogan and Stack)
- Packaging Technology using Oxygen Scavengers (Cotterman)

A *prima facie* obviousness rejection requires that the prior art include a motivation or suggestion for one of skill to combine or modify prior art references in a manner that would have caused the artisan to arrive at claimed subject matter. Legal requirements establish that it is not sufficient to merely identify different elements from among the prior art and then pick and choose only certain of those elements from among the entirety of separate teachings, then conclude that the combination would have been obvious.

There is nothing in Cotterman that would have provided a suggestion or motivation to its reader to use gamma irradiation in the range of approximately 35 kGy to 75 kGy in order to produce a bioresorbable, self-expanding stent with a controlled in vivo lifetime, according to the Applicants claims.

Cotterman is not directed to the preparation and use of stents, but rather is directed toward packaging technology. Cotterman describes using an oxygen scavenging system in combination with actinic radiation for packaging and sterilizing an oxygen sensitive product in a container (see Abstract). The use of gamma irradiation in Cotterman is merely described as one form of actinic radiation that can be used in conjunction with its packaging technology because actinic radiation should be applied to sterilize the container and trigger the oxygen scavenger in the article.

Cotterman, referring to paragraph [0043], provides only a generic list of potential "medical products" which includes "stents" among other disparate medical products such as needles, bandages, scalpels, ointments, plasma, intravenous solutions, shoe coverings, etc. The Office action has not presented any showing of a suggestion, motivation, or any other reason, as to why a stent -- particularly one that includes bioabsorbable material --

should be chosen among this lengthy list of disparate "medical products" to be subject to an amount of gamma irradiation in the range as recited in the present claims. The Office action's statement that Cotterman "specifically mentions stents in this same paragraph," provides nothing that supports a reasonable motivation or suggestion to combine the cited references to arrive at the claimed invention

The Office action does not contain a convincing line of reasoning as to why all of the features of Applicants' claims, in their claimed combinations, would have been obvious in view of the prior art. It is of course not sufficient to allow Applicants' own specification or claims to be used as a form, to re-construct the claimed combination of features, in hindsight, from individual features found to exist separately among different prior art references. However, the reconstruction of Applicants' claimed subject matter from these prior art references, the basis of the Office actions obviousness rejection, can only be explained upon review of the Applicants' specification and claims.

Furthmore, the Office action states that, "Hogan fails to disclose the stent as being gamma-irradiated. However, Cotterman et al. teach that a stent ([0043]) should be irradiated with gamma irradiation in the amount of 39 kGy in order to sterilize it effectively ([0098]). It would have been obvious to irradiate the Hogan stent with this amount of gamma irradiation so that it too would be sterilized."

Applicants' invention, however, uses gamma-irradiation to fine tune the in vivo functional life of the stents (see paragraphs [0045] and [0047]); sterilization, for example, by ethylene oxide, is described elsewhere in the application. Therefore, in view of the present invention, the Office action's assertion of obviousness is not supported.

In view of these remarks, Applicants respectfully assert that the requirements for properly establishing a *prima facie* case of obviousness have not been met. Applicants respectfully request that this rejection be withdrawn.

Claims 4-7, 12-15, 52-55, and 56

The Office action rejected claims 4-7, 12-15, 52-55, and 56 under 35 U.S.C. 103(a) as being obvious over a combination of Hogan, Stack, Cotterman, along with

other references. Specifically, Hogan in view of Stack and Cotterman and further in view of:

- Thompson et al. (U.S. Patent No. 5,957,974; herein referred to as "Thompson") were used to reject claims 5-7 and 13-15.
- Amstrup (U.S. Patent No. 5,476,508; herein referred to as "Amstrup") were used to reject claims 4 and 12.
- Turnlund et al. (U.S. Patent No. 5,629,077; herein referred to as "Turnlund") were used to reject claim 56.
- Shaolian et al. (U.S. Patent No. 6,261,316; herein referred to as "Shaolian") were used to reject claims 52-55.

Rejection of these claims is also traversed as failing to support a conclusion of *prima facie* obviousness for at least the reasons as described in the Applicants' response to the rejection of claims 1-3, 8-11, 16, 18-23, 50, 51, and 57.

Neither Thompson, Amstrup, Turnlund, nor Shaolian describe annealing and gamma-irradiating a bioresorbable stent by exposure to gamma irradiation in an amount in the range of approximately 35 kGy to 75 kGy.

Furthermore, with regard to the rejection of claims 52-55, the Office action has not addressed all of claimed features that are believed to be taught by Shaolin.

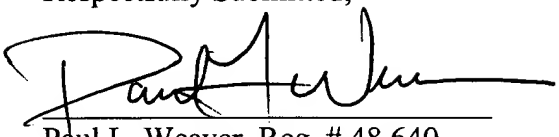
In particular, the Office action has not stated what portions of Shaolin are believed to specifically teach the particular self-expansion forces in relation to the lengths and diameters of the bioabsorbable stents in compressed and expanded states. With regard to compression resistance Shaolin is silent.

Accordingly, Applicants respectfully request that the rejection of claims 4-7, 12-15, 52-55, and 56 be withdrawn.

In view of the present amendments and remarks, Applicants submit that the outstanding rejections have been either overcome or should otherwise be withdrawn.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

By: 

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Dated: 10 June 05

PLW#17392